K043147

XJR-148-6534/bf

FEB 15 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

General information

Company Name:	Philips Medical Systems Nederland BV
Address:	Veenpluis 4-6 Best, Netherlands, 5684 PC
Registration No.:	1217116
Contact person:	Lynn Harmer Manager, regulatory Submissions Tel: (425) 487-7312 Fax: (425) 487-8666 Lynn.Harmer@Philips.com

Date Prepared:	9 November 2004
Device (Trade) Name:	**ACHIEVA family**
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification:	Class II
Product code:	LNH
Performance standards:	NEMA voluntary standards, FDA MR Diagnostic Device Guidance, UL and IEC 601 appropriate safety standards and/or draft standards are used.

Predicate Device(s):

The Philips Medical Systems ACHIEVA is the successor of the already cleared (predicate device) INTERA ACHIEVA family release 1-series (ref.K031815).

Indications for use:

The **ACHIEVA family** consists of diagnostic devices that produce cross-sectional images, spectroscopy images and/or spectra in any orientation of the internal structure of the whole body. These images when interpreted by a trained physician, yield information that may assist in diagnosis.

Device description:

The ACHIEVA family is the successor of the predicate Intera Achieva family release 1-series.

The design of ACHIEVA family is based on the same software platform and hardware technology as its predicate device. All MR system parts of the ACHIEVA family have the same appearance.

The ACHIEVA family is extended with enhancements and new functionalities for contrast enhanced MRA techniques and faster scanning techniques. Furthermore it is extended with SENSE Body wrap coil RF-coil and extension of multi-nuclei spectroscopy with 3T coils.

General Safety and Effectiveness

The ACHIEVA family does not induce any other risks than already indicated for its predicate device with the same safety and effectiveness.

Substantial Equivalence

It is the opinion of Philips Medical Systems that the Philips **ACHIEVA family** is substantially equivalent to its predicate device Intera Achieva.

End

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 5 2005

Mr. Lynn T. Harmer
Manger, Regulatory Submissions
Phillips Medical Systems North America
22100 Bothell Evert Highway
Post Office Box 3003 98141-3003
BOTHELL WA 98021-8431

Re: K043147
Trade/Device Name: Achieva Family
Regulatory Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: January 10, 2005
Received: January 12, 2005

Dear Mr. Harmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K04 3147

Device Name : **ACHIEVA family**

Indication For Use :

ACHIEVA family consists of diagnostic devices that produce cross-sectional images, spectroscopy images and/or spectra in any orientation of the internal structure of the whole body. These images when interpreted by a trained physician, yield information that may assist in diagnosis.

Prescription Use ___X____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043147